W is -OH, -N-R3R4, or OR5, where R3, R4, and R5 , independently, is H, C1-C12 alkyl, C6-C18 aryl, Cl-C12 acyl, C7-C18 aralkyl, or C7-C18 alkaryl, or a pharmaceutically acceptable salt thereof; and

each bond between two amino acids or amino acid derivatives, represented by a dash ("-"), can be either a peptide bond or a pseudopeptide bond.

In the abstract:

At page 58, in the abstract, please delete the heading "Background of the Invention".

REMARKS

Sequence listing

The Examiner has stated that the CFR submitted by the Applicants includes an error which requires the appropriate correction. In response, Applicants herewith provide a new sequence listing and CFR containing all the sequences. Applicants now submit that they comply with the requirements of the sequence rules of 37 CFR Sections 1.81-1.825.

Abstract

The Examiner has objected to the phrase "Background of the Invention" at page 58 of the abstract of the invention. In response, Applicants have amended the abstract to delete this phrase.

Claim objection

The Examiner has objected to claim 40 because of the use of the terms "CaMe-Trp", "CaMe-Glm", "N-Me-Arg", and "Lys-e-NH-R". The Examiner states that the position of the substituent, α or ε, should be indicated in the term. In response, the Applicants have amended claim 40 in order to indicate the position of these substituents.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 40-52 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner points to the phrase "each bond between two amino acids, represented by a dash '-' can be either a peptide bond or a pseudopeptide bond, or a pharmaceutically acceptable salt". The Examiner objects to this term as rendering the claim indefinite because it is not clear how a bond between two amino acids can be a pharmaceutically acceptable salt. In response, Applicants have amended claim 40 to remove "pharmaceutically acceptable salt" as a bond.

The Examiner has also rejected claims 40-52 under 35 U.S.C. § 112, second paragraph, as indefinite because of the use of the term "any Trp derivative". In response, Applicants have amended claim 40 to specifically denote those Trp derivatives to be encompassed by the phrase "any Trp derivative".

The Examiner has also rejected claim 43 under 35 U.S.C. § 112, second paragraph, for reciting the limitation "amino acid derivatives" in that there is insufficient antecedent basis for this limitation in the claim. In response, Applicants have amended claim 40 to include the appropriate antecedent basis for claim 43.

In view of the above, and in view of the claims as presently amended, Applicants respectfully request that the Examiner withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

The Examiner has rejected claim 40 under 35 U.S.C. § 102(b) as being anticipated by Koenig et al., European Patent 288965 (the Koenig '965 patent). In particular, the Examiner points to compound nos. 2, 3, 14, 40, and 43 of the Koenig '965 patent as being included within claim 40 of the instant application, thus anticipating claim 40. In particular, the Examiner has stated that claim 40 recites A2 as being Lys-e-NH-R, where R can be hydrogen, thus forming a lysine residue. In order to overcome this rejection, Applicants have amended claim 40 to remove the lysine residue from the A2 position. Applicants thus submit that claim 40, as presently amended, is not anticipated by the Koenig '965 patent, and thus respectfully request withdrawal of this rejection.

Conclusion

For the foregoing reasons, Applicants submit that all claims are patentable and a Notice of Allowance is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Applicants believe that no fee is due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to deposit account no. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

40. A compound having the formula:

R1
|
A1-A2-A3-W
|
R2

wherein:

each R1 and R2, independently, is H, C1-C12 alkyl, C6-C18 aryl, C1-C18 acyl, C7-C18 aralkyl, C7-C18 alkaryl or a dihydrotrigonellinate group;

A1 is a D or L-amino acid selected from the group consisting of Cys, Leu, Dap, Trp, Gln, a tethered amino acid with an indole ring, Phe, Hyp, [any Trp derivative;] a derivative of Trp selected from the group consisting of N-Me-Trp, nor Trp, beta Me-Trp, 2-Cl-Trp, and 5-X-Trp where X is selected from the group consisting of CN, Br, NH_2, COOH, CH_2NH_2 and CH_2-CH_2NH_2; [CaMe-Trp, CaMe-Gln] CαMe-Trp, C[a]αMe-Gln, Des-amino-Trp, Pyr, Bth, Nal, Tcc, Asn, Nva, Abu, Tyr, Tic-OH, Phe, Tip, and Dip;

A2 is a D or L-amino acid selected from the group consisting of Cys, Trp, Arg, [N-Me-Arg] Nα-Me-Arg, CαMe-Arg, Orn, Cit, hArg(R)2, where R is selected from the group consisting of hydrogen, alkyl, aryl, aralkyl, or alkylaryl, [Lys-e-NH-R] Lys-ε-NH-R, where R is selected from the group consisting of [hydrogen] alkyl, aryl, aralkyl, or alkylaryl; A3 is a D or L-amino acid selected from the group

consisting of Glu, N-Me-Tyr, CαMe-Tyr, Tic-OH, Tic, Dip, Trp, Phe, des-carboxylic-Tyr (tyramine), and Tyr-(R), where R is hydrogen or a lipophilic group; W is -OH, -N-R3R4, or OR5, where R3, R4, and R5 , independently, is H, C1-C12 alkyl, C6-C18 aryl, Cl-C12 acyl, C7-C18 aralkyl, or C7-C18 alkaryl, or a pharmaceutically acceptable salt thereof; and

each bond between two amino acids or amino acid derivatives, represented by a dash ("-"), can be either a peptide bond or a pseudopeptide bond [or a pharmaceutically acceptable salt thereof].

In the abstract:

COMPOUNDS FOR CONTROL OF APPETITE, BLOOD PRESSURE, CARDIOVASCULAR RESPONSE, LIBIDO, AND CIRCADIAN RHYTHM

Ambikaipakan Balasubramanium
William T. Chance

[Background of the Invention]

This invention relates generally to dipeptides and tripeptides and to methods for pharmaceutical treatment of mammals using analogs of such dipeptides and tripeptides. More specifically, the invention relates to tripeptides and their analogs, to pharmaceutical compositions containing such dipeptides and tripeptides and to methods of treatment of mammals using such dipeptides and tripeptides. In addition, the invention relates to methods of treatment of mammals using such dipeptides and tripeptides for control of appetite, blood pressure, cardiovascular response, libido, and circadian rhythm.